IMPACT OF PHARMACIST HOMECARE SERVICE ON MEDICATION ADHERENCE AND KNOWLEDGE AMONG HYPERTENSIVE PATIENTS IN SEREMBAN

by

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DEDICATION

I would like to dedicate this work with lots of love to my husband Zainudin bin Hj. Selamat and my lovely daughter Nur Amanina Zahra who constantly give the moral support and love that energizes me to pursue and accomplish my goals.

Azuwana

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      ii. **"Medication counselling beyond institution: Impact of pharmacist home counselling session on hypertensive patients' blood pressure control"** at Pharmacy R&D Conference 2008 organized by Ministry of Health. (Second Best Poster)

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LIST OF ABBREVIATIONS

ACEI	Angiotensin Converting Enzyme Inhibitors
Aldo-ANT	Aldosoterone Antagonist
ARB	Angiotensin Receptor Blocker
BB	Beta Blockers
BBC	The British Broadcasting Corporation
BMI	Body Mass Index
BP	Blood Pressure
BPH	Benign Prostatic Hypertrophy
CCB	Calcium Channel Blocker
CHD	Coronary Heart Disease
CHF	Chronic Heart Failure
CI	Confidence Interval
CVA	Cerebrovascular Accident
DASH	Dietary Approaches to Stop Hypertension
DBP	Diastolic Blood Pressure
DDD	Defined Daily Dose
HbA1c	Hemoglobin A1c
HCTZ	Hydrochlorothiazide
JNC 7	Seventh Report of the Joint National Committee
LVH	Left Ventricular Hypertrophy
MOH	Ministry of Health, Malaysia
MYR	Malaysian Ringgit
NAPRA	National Association of Pharmacy Regulatory Authorities Canada
NHANES	National Health and Nutrition Examination Survey
NHS	National Health Service
NMUS	National Medicines Use Survey
NST	News Strait Times
OR	Odds Ratio

RPSGB	The Royal Pharmaceutical Society of Great Britain
SBP	Systolic Blood Pressure
SD	Standard Deviation
SE	Standard Error
SPSS	Statistic Package for Social Sciences
UK	United Kingdom
US	United States of America
USD	United States' Dollar
WHO	World Health Organization

IMPAK LAWATAN DAN PERKHIDMATAN FARMASI DI RUMAH TERHADAP KEPATUHAN DAN PENGETAHUAN UBAT-UBATAN DI KALANGAN PESAKIT-PESAKIT HIPERTENSI DI SEREMBAN

ABSTRAK

Hipertensi merupakan salah satu masalah kesihatan yang kronik di Malaysia berikutan peratusan pengidapnya yang tinggi (42.6% dalam tahun 2006), kurangnya kesedaran terhadap penyakit ini dan kesannya terhadap kadar morbiditi dan mortaliti. Tahap keakuran rawatan perubatan yang rendah merupakan antara penyebab utama kegagalan kawalan penyakit hipertensi. Oleh itu penyelidikan ini dijalankan bagi menilai tahap keakuran pesakit terhadap rawatan perubatan, kawalan tekanan darah dan tahap pengetahuan melalui 'Perkhidmatan Perawatan Farmasi di Rumah'. Penyelidikan ini dimulakan pada bulan April hingga November 2007 di Daerah Seremban, Negeri Sembilan di mana 121 pesakit hipertensi dari Hospital Tuanku Jaafar Seremban telah dipilih. Borang soal selidik berstruktur telah digunakan dalam penyelidikan ini manakala tekanan darah diambil dengan menggunakan alat pengukur automatik yang telah dikalibrasi (Microlife BP, Model 2BH0). Seratus tiga pesakit telah menjalani penyelidikan ini sepenuhnya di mana 53 pesakit diletakkan dalam kumpulan intervensi manakala 50 lagi dalam kumpulan kawalan. Min (sisihan piawai) umur dikalangan peserta adalah 62.2 (10.1) tahun bagi kumpulan intervensi dan 59.4 (9.4) kumpulan kawalan. Majoriti peserta terdiri daripada wanita (56.3%) dan berbangsa Melayu (59.2%). Hasil kajian kumpulan intervensi, didapati peratus keakuran pesakit terhadap rawatan perubatan meningkat sebanyak 7.6% selepas sesi kaunseling pertama. Selepas

sesi lawatan dan pendidikan, peratusannya meningkat sebanyak 30.1%. Jumlah peningkatan peratusan keakuran terhadap rawatan perubatan dari fasa pengambilan hingga fasa akhir adalah sebanyak 37.7%. Ini berbeza daripada kumpulan kawalan di mana peningkatan sebanyak 4.0% sahaja. Bagi tekanan darah pula, hasil penyelidikan menunjukkan tiada perbezaan yang signifikan didapati dalam kumpulan kawalan manakala kumpulan intervensi pula menunjukkan penurunan tekanan darah yang sangat signifikan ($p<0.05$) di mana min (sisihan piawai) tekanan darah sistolik menurun daripada 147.0 mmHg (23.9) kepada 135.9 mmHg (21.8) $p<0.05$ dan min tekanan darah diastolik pula daripada 86.8 mmHg (17.7) kepada 81.5 mmHg (14.2) $p<0.05$. Penyelidikan berkaitan kesedaran dan pengetahuan terhadap penyakit dan rawatan pula, kumpulan intervensi menunjukkan peningkatan yang signifikan setelah menjalani sesi kaunseling, perundingan dan pendidikan di rumah. Kesemua 6 soalan tersebut menunjukkan peningkatan lebih daripada 30%. Kesimpulannya, program farmasi seperti Perkhidmatan Rawatan Farmasi di Rumah telah terbukti dapat meningkatkan tahap keakuran terhadap rawatan perubatan, pengetahuan pesakit dan seterusnya mengurangkan tekanan darah pesakit-pesakit hipertensi di Seremban.

Kata kunci: hipertensi, tekanan darah, kepatuhan , lawatan rumah pesakit, farmasi, pendidikan pesakit, pengetahuan

IMPACT OF PHARMACIST HOMECARE SERVICE ON MEDICATION ADHERENCE AND KNOWLEDGE AMONG HYPERTENSIVE PATIENTS IN SEREMBAN

ABSTRACT

Hypertension is one of the major public health problems in Malaysia due to its high prevalence (42.6% in 2006), lack of awareness amongst the general population, its poor control and its impact on cardiovascular morbidity and mortality. A common reason for inadequate control of hypertension is low adherence with antihypertensive medicine regimen. Therefore, this research was conducted to assess and evaluate patients' adherence and to examine the impact of "Pharmacist Homecare Service (PHS)" provision on the patients' adherence, blood pressure reduction and knowledge among hypertensive patients. The research was conducted from April to November 2007 in Seremban, Negeri Sembilan. A total of 121 patients from Hospital Tuanku Jaafar Seremban were interviewed using a validated structured questionnaire and blood pressure was measured with a calibrated automated device (Microlife BP, model 2BH0). Upon consent, 60 patients were recruited into the normal counselling group (control group) and the other 61 patients were recruited into the PHS group (intervention group). At the end of study period, only 103 participants completed the 6 months study, 53 in the intervention group and the rest in the control group. The mean (SD) age of the study population was 62.2 (10.1) years for the intervention group and 59.4 (9.4) years in the control group. Most of the patients were female (56.3%) and Malay ethnics constituted the majority of patients

(59.2%). In the intervention group, percentage of adherence increased by 7.6% after normal counselling during recruitment; and increased by 30.1% after education session during home visit. The increment of adherence from recruitment to final assessment (home visit 2) was 37.7%. Whereas in the control group, percentage of adherence only increased by 4.0% after normal counselling during recruitment. There were no significant different in mean blood pressure of control group ($p>0.05$) whereas in the intervention group there was significant reductions ($p<0.05$) in the systolic blood pressure mean (SD) from 147.0 mmHg (23.9) to 135.9 mmHg (21.8) $p<0.05$ and diastolic blood pressure mean from 86.8 mmHg (17.7) to 81.5 mmHg (14.2) $p<0.05$. For awareness and knowledge of disease and therapy, the intervention group showed significant difference between the knowledge assessments with regard to the consultation, counselling and patients' education in the intervention group. The percentage of knowledge for all questions was increased by more than 30%. Therefore, a pharmacy care program such as "Pharmacist Homecare Service" leads to increases in medication adherence, medication persistence, knowledge and clinically reductions in blood pressure among hypertensive patients in Seremban.

Keywords: hypertension, blood pressure, adherence, home visit, pharmacist, patient education, knowledge

CHAPTER 1

INTRODUCTION

CHAPTER 1

INTRODUCTION

1.1.0 Pharmaceutical Care

1.1.1 Introduction

The role of pharmacist in the healthcare system had changed over the last two decades. Pharmaceutical care is a way of dealing with patients and their medication. It is a concept that deals with the way people should receive and use medication, and instructions for the use of medicines. It also deals with responsibilities, medication surveillance, counselling, outcomes of care, information about disease states and lifestyle issues.

Pharmaceutical care concept was first described by Mikeal et al. as 'the care that a patient requires and receives which assures safe and rational use of drugs' (Mikael et al., 1975). Brodie and colleague were the first to give a more complete definition of pharmaceutical care. They stated 'pharmaceutical care includes the determination of the drug needs for a given individual and the provision not only the drugs required but also of the necessary services (before, during or after treatment) to assure optimally safe and effective therapy (Brodie et al., 1980). It includes a feedback mechanism as a means of facilitating continuity of care by those who provide it.

In 1987, Hepler formulated his first definition of pharmaceutical care which the commitment to the patient became apparent: 'a covenantal relationship between a patient and a pharmacist in which the pharmacist performs drug-use-control functions (with appropriate knowledge and skill) governed by awareness of and commitment to the

patients' interest' (Hepler, 1987). It is designed to improve the quality of care of patients and improve their quality of life.

Strand, in 1992, published a new definition with Cipolle and Morley, in which the patients' central position in the process receives even more emphasis. 'Pharmaceutical Care is that component of pharmacy practice which entails the direct interaction of the pharmacist with the patient for the purpose of caring for patients drug-related needs' (Strand et al., 1992). In 1997, she redefined pharmaceutical care as: 'A practice for which the practitioner takes responsibility for a patient's drug therapy needs and is held accountable for this commitment' (Van Mil, 2000).

The goal of pharmaceutical care is to improve and individual patients' quality of life through achievement of definite medication-related therapeutic outcome. This involves three major functions (American Society of Hospital Pharmacists, 1993):

a. identifying potential and actual medication-related problems
b. resolving actual medication-related problems
c. preventing potential medication-related problem

In pharmaceutical care, the direct relationship between an individual pharmacist and an individual patient is that of a professional covenant in which the patient's safety and well-being are entrusted to the pharmacist, who commits to honouring that trust through competent professional actions that are in the patient's best interest. Although pharmaceutical care has been accepted among pharmacy professionals but there are some barriers to the provision of pharmaceutical care (Van Mil, 2000). These barriers are outlined in Table 1.1.

Table 1.1: Barriers to the provision of pharmaceutical care (Van Mil, 2000)

A	Resources	1	Lack of money (reimbursement)
		2	Lack of time
		3	Lack of space in pharmacies
		4	Lack of software for medication assessment
		5	No clinical patient data available
		6	Lack of trained staff
		7	Lack of protocols or consensus reports for treatment
B	Attitude and opinions	1	Attitude/opinion of staff
		2	Attitude/opinion of other professionals
		3	Attitude/opinion of practicing pharmacists (product orientation)
		4	Attitude of pharmacy owner (the boss)
		5	Lack of vision on professional development
C	Education	1	Lack of clinical education
		2	Lack of education in communication skills
		3	Lack of education in social pharmacy
		4	Lack of education on health systems/public health
D	Skills	1	Lack of skills for medication assessment
		2	Lack of communication skills of pharmacist
		3	Lack of documentation skills of pharmacists
		4	Lack of management skills
E	Environment	1	Legal barriers
		2	National health care structure in general
		3	Inertia of pharmacists as a group
		4	Privacy problems

Pharmaceutical care is applicable and achievable by pharmacists in all practice settings. It is not a matter of formal credentials or place of work (American Society of Hospital Pharmacists, 1993). It is a matter of a direct personal, professional, responsible relationship with a patient to ensure that the patient's use of medication is optimal and leads to improvements in the patient's quality of life. Pharmacists should commit themselves to continuous care on behalf of individual patients. They bear responsibility for ensuring that the patient's care is ongoing despite work-shift changes, weekends and holidays.

1.1.2 Homecare Service (Community Outreach / Home Visit)

Homecare service refers to health services, health education and health promotion strategies directed to the entire population, specifically to high risk and underserved groups and individuals (Hill et al., 2000). It is an activity at the interface of medicine and public health, an area that is the focus of community nursing. Its goal is to reach those who have not been reached by usual methods for the purpose of gaining knowledge, information, and access to and utilization of health services. Homecare service is an essential component of comprehensive programs to promote health, as well as prevent and/or control disease and related risk factors (Hill et al., 2000). The key principles are active community participation and partnership, planning program implementation and evaluation. Effective interventions combine persuasive communications, interpersonal relationships, skills training and community organizing (Hill et al., 2000). It has proved hypertension control by linking health profession-healthcare organizations, and current or potential patients with resources in patients' communities.

Clinical hypertension care and control programs, which include community outreach, provide three important lessons (Alvarez et al., 2001):

a. Clinicians can use resources in the community to directly enhance their care of patients, thus improving long-term control of hypertension and reducing associated target organ damage
b. Community programs provide reinforcement of the clinician's recommendation and teaching efforts
c. Physicians, nurses and other health care providers can provide homecare services which include screening, case finding, referral, education, and monitoring and

leadership by accepting referrals, promoting outreach programs, and acting as consultants

1.1.3 Role of Pharmacists in Home Care Services: A Literature Review

Lowe and colleagues in the year 2000 had conducted a medication review study for older people in a suburban area of Leeds (Lowe et al., 2000a). Patients fulfilling the inclusion criteria were recruited and randomly allocated to the intervention or control group and received three visits from a clinical pharmacist. One hundred and fifty two patients completed the study; 73 patients in the intervention group who received medication review and educational; and 79 patients in the control group received standard medical care. The adherence score for patients in the intervention group was 91.3% (95% CI: 88.7 to 93.9) and control group 79.5% (95% CI: 74.7 - 84.3); $p<0.0001$. The overall change in knowledge for both groups between the first and third visit was highly significantly different between the two ($p<0.0001$).

The study shows that medication review and patient education by pharmacist in the community can significantly improve patient's knowledge of and adherence with medication in short term. By combining a medication review with in-depth medicine education, the program offers a way of maximizing the benefits that patients can receive from their medicines. Pharmacist was also able to negotiate the medication regimen with the patient and doctor.

A cross-sectional study was done by Sorensen and colleagues in 2005 to determine the association between medication-related risk factors and poor patient health outcomes from observations in the patients' homes (Sorensen et al., 2005). Two hundred

and four patients were visited in this study. Overall, recent worsening of health status was seen in 55 (27.0%) patients and 51 (25.0%) patients experienced an adverse drug event over the preceding 3 months. Of the medication-related risk factors examined, patients were most frequently confused by generic and trade names (114 patients or 55.9%) while poor adherence was reported by 107 (52.5%) patients. Some 68 (33%) patients risked therapeutic duplications and some patients had more than one duplicated set of items. The most frequently duplicated items were cardiovascular medications. In conclusion, the major findings of this study include the identification of considerable relationships between the medication-related risk factors and health outcomes which support the theory that polypharmacy and medication-related risk factors as a result of polypharmacy are correlated with poor health outcomes.

Another study also was done by Sorensen and colleagues in 2006 to determine the prevalence and inter-relationships of medication-related risk factors for poor patient health outcomes identifiable through 'in-home' observation (Sorensen et al., 2006). Home visits were conducted at 204 patients' house by pharmacists (87.3%) or general practitioners (12.7%) as part of the intervention in a randomized controlled trial. Of the medication related risk factors examined, patients were most frequently confused by generic and trade names (55.9% of patients) while poor adherence was reported with the second highest frequency (52.5%). These medication related risk factors could be improved by counselling and education programme. In conclusion, visiting patients' homes may identify medication related risk factors and inter-relationships that may no be evident by other methods.

1.2.0 Epidemiology of Hypertension

Hypertension, most commonly referred to as “high blood pressure”, is a medical condition in which the blood pressure is chronically elevated. Hypertension is usually first considered during periodic check-up visits or as part of ordinary screening when patients are seen for unrelated minor illness. The initial evaluation should consist of a careful medical history, appropriately comprehensive physical examination and necessary tests.

The most recent definition of hypertension as released by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7) (Chobanian et al., 2003) is a systolic blood pressure ≥140mmHg or diastolic blood pressure ≥ 90mmHg. Systolic pressure is the highest arterial pressure during the contraction of the left ventricle of the heart and diastolic pressure is the lowest arterial pressure during relaxation and dilatation of the ventricles of heart when it refills with blood. Perhaps the most important change is the new classification of “pre-hypertension” (SBP 120 -139mmHg or DBP 80 - 89mmHg). Table 1.2 shows the classification of blood pressure according to JNC7. Pre-hypertension is not a disease category, it is a designation chosen to identify individuals at high risk of developing hypertension, so that both patients and clinicians are alerted to the risk and encouraged to intervene and prevent the delay of disease from developing. After evaluating hypertensive patients, decisions will be made regarding goals for treatment and strategies for achieving these goals.

Table 1.2: Blood Pressure Classification According to JNC 7 (Chobanian et al., 2003)

BP Classification	SBP mmHg	DBP mmHg
Normal	<120 and	<80
Pre-hypertension	120-139 or	80-89
Stage 1 Hypertension	140-159 or	90-99
Stage 2 Hypertension	≥160 or	≥ 100

In general, some combination of lifestyle change and drug therapy will be recommended. When the pressure is higher, drug treatment will be started immediately. For those with pressures in the range of 140 to 150mmHg systolic and 90 to 100mmHg diastolic, without target organ damage, initial non-pharmacologic choices, particularly weight reduction, with or without reduced salt intake may be appropriate.

1.2.1 Causes of hypertension

The exact causes of hypertension are not known. Several factors and conditions may play a role in its development, including overweight (obesity), lack of physical activity, too much salt in the diet, smoking, excessive alcohol consumption, stress, old age, genetics, family history of high blood pressure, chronic kidney disease and adrenal and thyroid disorders.

A study by Anderson and Slocum-Dickson Medical Group shows that increased age is associated with a significant increase in the prevalence of hypertension and especially of systolic hypertension after age 60 years. Increased obesity between ages 30-50 years is associated with significant increases in diastolic blood pressure (Anderson Jr. G.H. and Slocum-Dickson Medical Group, 1999).

Weight reduction and sodium reduction are recommended for all prehypertensive and hypertensive patients. In Trial of non-pharmacologic Interventions in the Elderly (TONE), reducing sodium to 80mmol (2g) per day reduced blood pressure over 30 months, and about 40% of those on the low-salt diet were able to discontinue their antihypertensive medications (Appel LJ et al., 2001). Weight loss of as little as 4.5kg reduces blood pressure and prevents hypertension in a large proportion of overweight persons, although the ideal is to maintain normal body weight (The Trials of Hypertension Prevention Collaborative Research Group, 1997).

Chronic hypertension is becoming increasingly common in adolescence and is generally associated with obesity, sedentary lifestyle, smoking and a positive family history of hypertension. Lifestyle interventions should be recommended for all children with hypertension, with pharmacological therapy instituted for higher levels of blood pressure or if insufficient response to lifestyle modifications occurs (Chobanian et al., 2003).

1.2.2 Sign and Symptoms

There are usually no symptoms or signs of hypertension. In fact, nearly one-third of those who have it, do not know it. The only way to know if you have hypertension definitely is, to have your blood pressure checked. Some people with severe high or a rapid rise in blood pressure may experience headaches, dizziness, fatigue, blurred vision, facial flushing and tinnitus (Bahagian Pendidikan Kesihatan, 2005).

1.2.3 Complication

While elevated blood pressure alone is not an illness, it often requires treatment due to its short and long term effects on many organs (Chobanian et al., 2003). Hypertension is usually accompanied by other cardiovascular risk factors and is metabolically linked to dyslipidemia, glucose intolerance, abdominal obesity and hyperinsulinemia. About half of the persons with hypertension have two or more other accompanying risk factors. The risk is increased for (Stamler et al., 1993):

a. Cerebrovascular accident (CVA or strokes)

b. Myocardial infarction (heart attack)

c. Hypertensive cardiomyopathy (heart failure)

d. Hypertensive retinopathy (damage to the retina)

e. Hypertensive nephropathy (chronic renal failure)

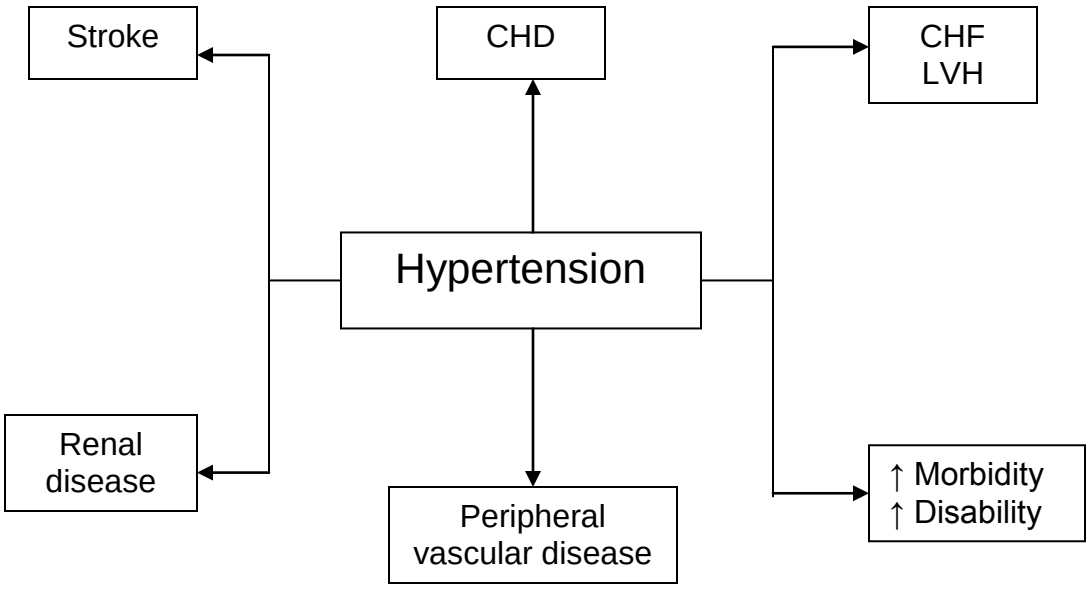

Figure 1.1: Hypertension: A significant cardiovascular and renal disease risk factor (CHD: coronary heart disease, CHF: chronic heart failure and LVH: left ventricular hypertrophy)

Hypertension represents a potent risk factor for cardiovascular, peripheral vascular and renal disease (Stamler et al., 1993, McMahon et al., 1990) The higher the blood pressure, the greater is the likelihood of myocardial infarction, heart failure, stroke, and kidney disease. According to the American Heart Association, cardiovascular disease is the number one killer in the United States. It been estimated that more than 2,600 people die of heart disease every day, which translates into one cardiovascular death every 33 seconds (Saunders, 2007). Each year, heart disease (30.4%) kills more Americans than cancer (23%) (Centers for Disease Control and Prevention, 2000) Until the year 2005, it was the number one cause of death and disability in the United States and most European countries.

1.2.4 White-coat Hypertension

A higher BP in the physician's presence compared with out-of-office BP was reported more than 60 years ago. Today, clinicians are far more familiar with this phenomena but uncertainty remains about the optimal management of these patients. The clinical importance of white-coat hypertension has been recognized and most consensus groups, recommend ambulatory monitoring for the patient with that diagnosis (Pickering, 1996). White coat hypertension is a phenomenon in which patients exhibit elevated blood pressure in a clinical setting but not when recorded by themselves at home. It is believed that this is due to the anxiety some people experienced during clinic visits. There are many potential advantages when white-coat hypertension was detected:

1. patients with white-coat hypertension may not require drug therapy and substantial cost savings may accrue,

2. a better diagnostic and prognostic risk assessment for individual patients may be possible and
3. clinical drug studies can exclude white-coat hypertensive who may not respond to drug therapy in the same manner as sustained hypertensive patients (Mansoor and White, 1994).

1.2.5 Hypertension Treatment

Non-pharmacological management plays an important role in the management of hypertension (Silaste et al., 2000). Hypertension is typically treated by making changes in lifestyle and with medication therapy. Lifestyle changes include losing weight, stopping smoking, eating a healthy diet such as the Dietary Approaches to Stop Hypertension (DASH) diet, which includes reducing sodium and getting sufficient exercise (Ministry of Health et al., 2008).

1.2.5.1 Lifestyle Modification

There is universal agreement about the role of lifestyle modification in the management of hypertension, including those with high-normal blood pressure, particularly where there is a strong family history. Lifestyle modifications can be difficult to apply in the population at large and in the long-term. The ability of non-pharmacologic interventions to reduce mortality and morbidity in hypertension has not been shown directly (Table 1.3). Application of lifestyle intervention should not delay the introduction of drug therapy, especially in high-risk patients.

Lifestyle measures that helps to reduce blood pressure include (Williams et al., 2004a):

a. Weight reduction
b. Reduced salt, total fat and saturated fat intake
c. Limitation of alcohol consumption and cessation of smoking
d. Increased physical activity
e. Increased fruit and vegetable consumption

Weight loss of as little as 4.5kg reduces blood pressure and/or prevents hypertension in a large proportion of overweight persons (The Trials of Hypertension Prevention Collaborative Research Group, 1997). Blood pressure is also benefited by adoption of the Dietary Approaches to Stop Hypertension (DASH) eating plan which is a diet rich in fruits, vegetables and low fat dairy products with a reduced content of cholesterol (U.S. Department of Health and Human Services, 2006). Combination of two or more lifestyle modifications can achieve even better results (Chobanian et al., 2003).

Table 1.3: Lifestyle Modifications To Prevent and Manage Hypertension* (Chobanian et al., 2003)

Modification	Recommendation	Approximate SBP Reduction (Range)**
Weight reduction	Maintain normal body weight (body mass index 18.5-24.9kg/m²)	5-20 mmHg / 10kg
Adopt DASH eating plan	Consume a diet rich in fruits, vegetables, and low-fat dairy products with a reduced content of saturated and total fat	8-14 mmHg
Dietary sodium reduction	Reduce dietary sodium intake to no more than 100 mmol per day (2.4 g sodium or 6 g of sodium chloride	2-8 mmHg
Physical activity	Engage in regular aerobic physical activity such as brisk walking (at least 30 minutes per day, most days of the week)	4-9 mmHg
Moderation of alcohol consumption	Limit consumption to no more than 2 drinks per day in most men and to no more than 1 drink per day in women and lighter-weight persons	2-4 mmHg

Note: * For overall cardiovascular risk reduction, stop smoking
**The effects of implementing these modifications are dose and time dependent and could be greater for some individuals

1.2.5.2 Medication Therapy

The ultimate public health goal of antihypertensive therapy is to reduce cardiovascular and renal morbidity and mortality. The aim of treatment should be blood pressure control to <140/90mmHg for most patients, and lower in certain context such as diabetes or kidney disease (<130/80mmHg). Therapy begins with lifestyle modification, and if the blood pressure goal is not achieved, thiazide-type diuretics should be used as initial therapy for most patients, either alone or in combination with one of the other classes (Table 1.4). There are many classes of medications for treating hypertension, called antihypertensive which act by lowering blood pressure. The JNC-7 guidelines

recommend initiating two antihypertensive agents for patients whose systolic BP is 20mmHg above their goal. Commonly used medications for the treatment of hypertension in Malaysia include (Ministry of Health et al., 2002, Ministry of Health et al., 2008):

a. Diuretics

The use of diuretics is well established in the treatment of hypertension, cheap and the most widely used antihypertensive agents (Ministry of Health et al., 2008). They help the kidneys eliminate sodium and water from the body (decreases blood volume). Diuretics may be used as initial therapy. They also enhance the efficacy of other classes of antihypertensive drugs when used in combination (Sulaiman et al., 2001). Thiazide diuretics are one of the most widely used antihypertensive agents. In the elderly with no co-morbid conditions, diuretics are the drugs of choice in the treatment of systolic-diastolic hypertension and isolated systolic hypertension. Diuretics not only reduce the incidence of fatal and non-fatal strokes but also cardiovascular morbidity and mortality (Brown et al., 2000). In The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) study, which involved more than 40 000 hypertensive individuals,109 there were no differences in the primary CHD outcome or mortality between the thiazide-type diuretic chlorthalidone, the lisinopril or the amlodipine (The ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group, 2002). Examples of diuretics include frusemide, chlorothiazide, hydrochlorothiazide and indapamide. Common side effects are frequent

urination, muscle cramps, tiredness, dizziness, headache, dehydration, nausea, vomiting and sore throat.

b. Alpha Blockers

The peripheral alpha 1-adrenergic blockers lower blood pressure by reducing peripheral resistance, prostatic and urethral smooth muscle tone and provide symptomatic relief for patients with early benign prostatic hypertrophy (BPH) (Gillenwater et al., 1995). Examples of alpha blockers include doxazosin, prazosin and terazosin. Postural hypotension is a commonly known side effect especially at the initiation of therapy.

c. Beta Blockers (BB)

Beta blockers have long been established in the treatment of hypertension with angina, tachyarrhythmias or previous myocardial infarction where they have been shown to reduce cardiovascular morbidity and mortality (Ministry of Health et al., 2008). Certain beta blockers such as carvedilol and bisoprolol have been shown to be beneficial in patients with heart failure. Beta blockers are contraindicated in patients with obstructive airways disease, severe peripheral vascular disease and heart block. Examples of beta blockers include atenolol, bisoprolol, carvedilol, labetalol, metoprolol and propanolol. Common side effects are drowsiness, weakness, dizziness, dry mouth, eyes and skin, cold hands and feet, slow heartbeat, nightmares and erectile dysfunction.

d. Angiotensin Converting Enzyme Inhibitors (ACEIs)

ACEIs are effective in lowering blood pressure, well tolerated and do not have adverse effects on lipid and glucose metabolism. ACEIs have been shown to reduce mortality and morbidity in patients with congestive heart failure (The SOLVD Investigators, 1992), post myocardial infarction and cardiovascular risk patients with reduced left ventricular ejection fraction (The AIRE Investigator, 1993). In diabetic patient, ACEIs have been shown to reduce cardiovascular mortality, proteinuria and retard the progression of renal disease. Examples of ACEIs include captopril, enalapril, fosinoprol, lisinopril, perindopril, quinapril and ramipril. The common side effect is persistent dry cough.

e. Calcium Channel Blockers (CCBs)

Long-acting CCBs have been shown to be safe and effective in lowering blood pressure, both as first-line agents and in combination with other classes of antihypertensive drugs (Dahlof et al., 2005, Julius et al., 2004). It may also be useful in treating hypertensives with coronary heart disease (Davis et al., 2002). Examples of CCBs include amlodipine, diltiazem, felodipine, nifedipine and verapamil. Common side effects are headache, nausea, vomiting, ankle oedema and flushes on the face.

f. Angiotensin Receptor Blockers (ARB) / Angiotensin II Antagonists

ARBs are specific angiotensin II receptor antagonists with many properties similar to those of ACEIs. Unlike ACEIs, persistent dry cough is less of a problem. ARBs are beneficial in the treatment of early and advanced type 2 diabetic nephropathy (Brenner et al., 2001) and may reduce the incidence of major cardiac events in patients with heart failure (McMurray et al., 2003) hypertensive LVH and diastolic heart failure (Yusuf et al., 2003). Examples of ARBs include candesartan, irbesartan, losartan, telmisartan and valsartan.

g. **Combination Products** (usually contain hydrochlorothiazide (HCTZ) and one other drug)

Although effective blood pressure control can be achieved in most patients who are hypertensive, more than two-thirds of hypertensive individuals cannot be controlled on one drug and will require two or more antihypertensive agents selected from different dug classes. In ALLHAT, 60% of those blood pressure was controlled to <140/90 mmHg received two or more agents and only 30% overall were controlled on one drug (Cushman WC et al., 2002). Using two complementary antihypertensive agents in combination will always result in greater efficacy and fewer side effects than high-dose monotherapy (Neutel JM, 2006).

1.2.5.3 Current Antihypertensive Prescribing Practices

In the United States, a study compared National Health and Nutrition Examination Survey (NHANES) III 1988 –1994 (n=4933) and NHANES 1999–2002 (n=3249) data was done by Gu and colleagues to understand current medication utilization patterns among hypertensive, this study to examine trends and patterns of antihypertensive medication use among US adults with hypertension (Gu et al., 2006). Between 1988–1994 and 1999–2002, ACE inhibitor monotherapy use significantly increased from 6.2% to 8.5%, whereas monotherapy use of a diuretic or BB decreased from 4.9% and 7.1% to 2.7% and 5.1%, respectively. When monotherapy and polytherapy were considered together, diuretics remained the most commonly used antihypertensive drug class during 1988–1994 (27.8%) and 1999–2002 (28.7%). Use remained stable across both time periods for most drug classes, except for ACE inhibitors, for which was significant increase in use (15.2% versus 23.8%). Overall, antihypertensive polytherapy use among hypertensive increased significantly between 1988–1994 and 1999–2002 from 29.1% to 35.8% (Figure 1). The used of polytherapies containing a CCB, BB, or ACEI substantially increased by 30%, 42%, and 68%, respectively.

In the United Kingdom, one survey of 21024 patients from England and Wales was done by Walley and colleagues to describe the management of newly diagnosed hypertension between January 1993 and December 1997, and were followed for 4 years (Walley et al., 2003). This survey showed that diuretics was the most widely prescribed first line treatments (32.0%) followed by beta blockers (22.2%). The continuation rates for first-line therapy declined most sharply over the first year (at which point average continuation rates reached 69%). Whilst these patterns were similar for the different classes

of drug, continuation rates for ACE inhibitors/ARB were significantly greater than for other classes at 18 and 48 months (P50.01, chi-squared=64.80 at 12 months and 130.04 at 48 months).

A study published in 2008 by Wong and colleagues analyzed 67,028 patients prescribed anti-hypertensive agents from government primary care clinics of Hong Kong from January 2004 to June 2007 (Wong et al., 2008). The study evaluated the prescribing patterns, discontinuation and switching profiles of antihypertensive agents and their associated factors in one Hong Kong Chinese population. The most commonly prescribed drugs were CCBs (49%), BBs (46%) and ACEIs (19%). Thiazide diuretic prescribing was low (13%) and on the decline (14% in 2004 to 12% in 2007). Prescribing of ACEIs was rising (16% in 2004 to 23% in 2007). Drug discontinuation was highest for BBs (21%) and lowest for CCBs (12%). The high rates of discontinuation in BBs remained apparent after controlling for confounding variables. Switching was less common than discontinuation and was most likely with thiazide diuretics.

In Malaysia, the National Medicines Use Survey (NMUS) conducted several surveys in order to capture data at the various levels of medicines supply and distribution system in the country. The surveys covered Ministry of Health Malaysia, private hospitals, university hospitals, private general practice and private pharmacy. In 2006, BBs were the most commonly prescribed antihypertensive medication (25.7DDD/1000 population/day) followed by the CCBs (19.4), ACEIs (15.3), diuretics (8.0) and ARBs (4.3) (Rahman and Ming, 2009). There were 3 drugs whose contribution each made up more than 10% of total utilization – metoprolol (12.3DDD/1000 population/day), atenolol (12.0) and nifedpine (11.6). Of these, 2 were BBs and one a CCB. These 3 drugs were used mainly in the public sector (88%). Overall, 80% of all antihypertensives were

utilised in the public sector and 20% in the private sector. The most popular drugs in the private sector were atenolol (3.0DDD/1000 population/day), amlodipine (2.0) and enalapril (1.0).

Table 1.4: Compelling indications for individual drug classes (Chobanian et al., 2003)

Compelling indication*	Recommended drugs					
	Diuretic	BB	ACEI	ARB	CCB	Aldo-ANT
Heart failure	√	√	√	√		√
Postmyocardial infarction		√	√			√
High coronary disease risk	√	√	√			√
Diabetes mellitus	√	√	√	√	√	
Chronic kidney disease			√	√	√	
Recurrent stroke	√		√			

Note: *Compelling indications for antihypertensive drugs are based on benefits from outcome studies or existing clinical guidelines; the compelling indication is managed in parallel with the blood pressure

1.3.0 Hypertension around the world

Hypertension is a massive health problem affecting about 20% of the adult population in most countries (Chalmers and Zanchetti, 1996). Approximately 50 million individuals in the United States and 1 billion worldwide are affected by hypertension (Chobanian et al., 2003). The Framingham Heart Study has estimated that individuals normotensive at age 55 years have a 90% lifetime risk of developing hypertension (Vasan

et al., 2002). Table 1.5 shows the prevalence of hypertension in 13 countries. Worldwide, high blood pressure is estimated to cause 7.1 million deaths, about 13% of the global fatality total. Across WHO regions, research indicates that about 62% of strokes and 49% of heart attacks are caused by high blood pressure (World Health Organization, 2002) .

Table 1.5: Prevalence of High Blood Pressure (SBP >140 mmHg, DBP >90 mmHg) by Age Group (World Health Organization, 2008)

Country	Age Group	Sex	Prevalence (%)
Australia	65 +	Both	39.6
United Kingdom	65+	Both	66.9
Canada	65+	Both	42.7
United State of America	18+	Both	21.1
China	18+	Both	18.8
India (Jaipur)	20+	Both	51.5
Russian Federation (Moscow)	25-64	Male Female	8.2-15 10.6-14.8
Japan	30+	Male Female	56.2 39.7
Saudi Arabia	30+	Both	25.4-26.8
Malaysia	30+	Both	32.9
Thailand	35+	Both	22.7
Indonesia	65+	Male Female	50.9 59.6
Singapore	60+	Both	56.1

Hypertension is a common problem, with a consistent and continuous risk of cardiovascular disease and stroke associated with rising blood pressure levels (Williams et al., 2004b). Furthermore, effective treatment of blood pressures has been shown to cause reductions in morbidity and mortality from cardiovascular disease and stroke. As high blood pressure is the most important risk factor for cardiovascular disease, it has

been calculated that by achieving the target of 140mmHg, there would be a reduction of 28-44% in stroke and 20-35% in ischaemic heart disease depending on the age (He and Mac Gregor, 2003). This would prevent approximately 21,400 stroke deaths and 41,400 ischaemic heart disease deaths each year – and these translate to approximately 42,800 strokes and 82,800 ischaemic heart diseases saved, making a total of 125,600 events saved per year in the United Kingdom alone (He and Mac Gregor, 2003).

1.3.1 Cardiovascular Disease

Hypertension is one of the major single risk factor contributing to the development of cardiovascular morbidity and mortality in the world. Figure 1.2 shows that an estimated 17.5 million people died from cardiovascular disease in 2005, representing 30% of all global deaths (World Health Organization, 2008). Of these deaths, 7.6 million were due to heart attacks and 5.7 million were due to stroke.

Around 80% of these deaths occurred in low and middle income countries. The major causes of cardiovascular disease are tobacco use, physical inactivity and an unhealthy diet (World Health Organization, 2008). If appropriate action is not taken, by 2015, an estimated 20 million people will die from cardiovascular disease every year, mainly form heart attacks and strokes.

In the United States of America, hypertension affects more than 60 million people at a cost exceeding US$ 8 billion (Kjellgren et al., 1995) and cardiovascular disease, primarily ischemic heart disease and stroke, are the leading causes of deaths. It accounts for about 40% of all deaths annually and it is estimated that more than 58 million people in the United States have some form of cardiovascular disease (Kjellgren et al., 1995). In

1999, the leading causes of death were cardiovascular and neoplasm for both males and females. About 4,700 deaths for 25-34 year olds, 48,600 deaths for 45-54 years olds and 60% of all deaths in the elderly population (60 years and older) (World Health Organization, 2008).

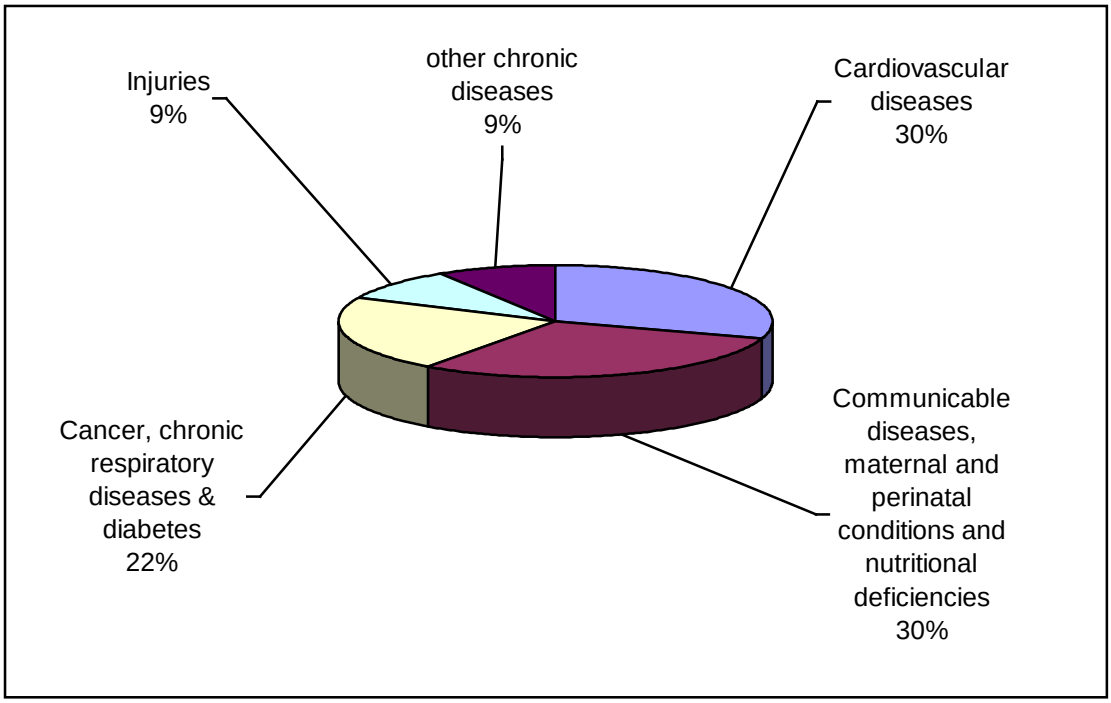

Figure 1.2: Percentage of global deaths by diseases (WHO, 2008)

In Canada, cardiovascular disease is also the leading cause of morbidity, mortality and hospitalization due to illness for men and women. In 1997, deaths from cardiovascular disease were 19,457 (37%). The mortality rate from cardiovascular disease was 263 per 100,000; females (258) and males (267) in 1998 (World Health Organization, 2008). .

1.3.2 Awareness, Treatment and Control of Hypertension in United States

The overall awareness of hypertension has improved from a level of 51% of Americans in the period 1979 to 1980 to 70% in 1999 to 2000 (Table 1.6). The percentage of patients with hypertension receiving treatment has increased from 31% to 59% the percentage of persons with high blood pressure controlled to below 140/90 mmHg has increased form 10% to 34% in the same period (Chobanian et al., 2003)

1.4.0 Hypertension in Malaysia

The Third National Health and Morbidity Survey 2006 (NHMS III) reported that the prevalence of hypertension in Malaysia was 42.6% (Institute for Public Health, 2008b) and the total utilization of antihypertensive was 73.5 DDD/1000 population/day; this means about 6-7% of the population were on drug treatment for hypertension (Rahman and Sivanandam, 2007). Among hypertensive patients, 35.8% were aware of their hypertension, 31.4% were currently on treatment and only 8.2% had controlled hypertension (Institute for Public Health, 2008b). Concerted public health effort is urgently required to improve the detection, treatment and control of hypertension in Malaysia. Malaysia, on the other hand is experiencing a rising incidence of cardiovascular disease and it has emerged as the principal cause of mortality and hypertension is a prevalent cardiovascular risk factor in our population (Kandiah et al., 1980, Osman et al., 1984). Based on Ministry of Health statistics, the leading causes of hospitalization in MOH hospitals for the year 2005 includes normal deliveries, followed by complications of pregnancy childbirth, accidents and diseases of circulatory system (Table 1.7). However, the major cause of deaths is due to septicaemia followed by heart disease (Table 1.8).